

REMARKS

Claims 1-10 are pending in the present application. Applicants would like to thank the Examiner for her time and comments during the telephone interview of August 20, 2002.

Rejections under 35 U.S.C. §112, second paragraph

Claims 1-7 have been rejected under 35 U.S.C. §112, second paragraph as being unclear. More specifically, claim 1 is asserted to be vague with the recitation of "foam-like." Claim 1 has been further amended for clarity to define the flow matrix as being "a porous polymer material...." Support for this amendment may be found on page 4, lines 8-10. With this amendment the material of the of the matrix is fully defined and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §102(b)

Claims 1-10 have been rejected under 35 U.S.C. §102(b) as anticipated by Pristoupil. Pristoupil is asserted to teach the use of a nitrocellulose membrane filters for chromatography and electrophoresis for the separation of proteins and nucleic acids. The Examiner further states on page 3, final sentence of Item 5, that

Pristoupil is considered to make obvious the instant claims because steps f1 through f2c of claim 1 are seen to be optional.

During the telephone interview, Applicants pointed out that claim 1 requires either step f1) or steps f2a-f2c), therefore steps f1 through f2c are not entirely optional. The Examiner clarified that her position is that steps f2a-f2c) are optional and that step f1) is disclosed in Pristoupil. The following comments are based on the clarifying comments of the Examiner.

Applicants traverse the rejection and withdrawal thereof is respectfully requested. The present invention, as encompassed by claim 1, is drawn to

A chromatographic assay method, comprising the steps of:

a) providing a polymeric membrane type flow matrix attached to a liquid-impervious backing, which flow matrix permits a capillary force assisted lateral flow there through, and at least a part of which flow matrix contains ion-exchange function, wherein the flow matrix has a foam-like structure with pores in the range of 0.01-20 μ m;

b) treating the flow matrix to reduce or eliminate nonspecific adsorption properties of the flow matrix;

c) applying to the flow matrix a sample containing at least two components;

d) initiating a first lateral flow of aqueous fluid to transport the sample through the flow matrix and separate the components therein;

e) interrupting said lateral flow; and either

f1) detecting at least one of said separated components on the flow matrix in the position reached by the respective component when the flow was interrupted; or

f2a) initiating a second flow of aqueous fluid to transport the components in a direction substantially transverse to the direction of the first lateral flow;
f2b) interrupting said second lateral flow; and
f2c) detecting at least one of said separated components on the flow matrix in the position reached by the respective components when the second lateral flow was interrupted.

The method of claim 1 requires in step a) that the matrix has ion-exchange function and in step b) that the flow matrix is treated to reduce or eliminate nonspecific adsorption properties of the flow matrix. Thus, the method of the present invention requires full chromatographic separation ability, i.e. specific ^{no} separation, with minimal non-specific adsorption. This is the exact opposite of the method of Pristoupil, which functions specifically through non-specific adsorption. As noted previously, the method of Pristoupil does not result in classical ^{yes it does} chromatography, i.e. a full separation of components based on some ^{= size} physical property. Rather as stated on page 114, final line, spanning page 115, the method of Pristoupil "makes it possible to achieve a simple group separation between such substances [low molecular weight components] and proteins...." As discussed on page 114, beginning at the 2nd full paragraph, the method of Pristoupil relies the non-specific adsorption of the proteins to the nitrocellulose to separate the components of the sample into only two zones, an adsorbed protein zone and a low molecular weight

component zone, that migrates with the front. Thus, there is no actual chromatographic, i.e. specific, separation of the components in Pristoupil. The differences between the present method and that of Pristoupil is further emphasized by a comparison of step b) of the invention to the disclosure on page 111, 1st full paragraph of Pristoupil. Step b) of the invention requires that the flow matrix be treated to reduce or eliminate nonspecific adsorption. With the method of Pristoupil the exact opposite is done and as stated on page 111, 1st full paragraph,

"manufacturers often add small amounts of additive, e.g. octanol, glycerine, detergents⁴⁶, etc., to the membranes in order to improve their mechanical, filtering, and flow characteristics. It is usually necessary to remove these additives by appropriate procedures." (emphasis added)

Thus, Pristoupil teaches that the membrane must be treated to increase adsorption, i.e. the exact opposite of the present method.

In summary, Pristoupil does not teach the method of the present invention because Pristoupil does not use specific separation of the components. Rather Pristoupil relies on the non-specific adsorption of proteins to separate them from low molecular weight components, which do not chromatograph, but migrate with the front of the flow. As such, Pristoupil does not anticipate the present invention and withdrawal of the rejection is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, Ph.D. (Reg. No. 40,069) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

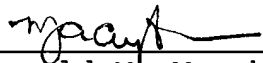
A marked-up version of amended claim 1, showing all changes, is attached hereto.

Applicants request a one (1) month extension of time for filing the present response. The required extension fee is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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MARKED-UP VERSION SHOWING CHANGES

IN THE CLAIMS

Claim 1 has been amended as follows.

1. (Twice Amended) A chromatographic assay method, comprising the steps of:

a) providing a polymeric membrane type flow matrix attached to a liquid-impervious backing, which flow matrix permits a capillary force assisted lateral flow therethrough, and at least a part of which flow matrix contains ion-exchange function, wherein the flow matrix ~~has a foam like structure with pores~~ is a porous polymer material with pores in the range of 0.01-20 μ m;

b) treating the flow matrix to reduce or eliminate nonspecific adsorption properties of the flow matrix;

c) applying to the flow matrix a sample containing at least two components;

d) initiating a first lateral flow of aqueous fluid to transport the sample through the flow matrix and separate the components therein;

e) interrupting said lateral flow; and either

f1) detecting at least one of said separated components on the flow matrix in the position reached by the respective component when the flow was interrupted; or

f2a) initiating a second flow of aqueous fluid to transport the components in a direction substantially transverse to the direction of the first lateral flow;

f2b) interrupting said second lateral flow; and

f2c) detecting at least one of said separated components on the flow matrix in the position reached by the respective components when the second lateral flow was interrupted.